K053218

DEC 2 8 2006

XI. 510(k) SUMMARY OF SAFETY & EFFECTIVENESS

PROPREIETARY NAME:	DBX® Demineralized Bone Matrix Putty DBX® Demineralized Bone Matrix Paste DBX® Demineralized Bone Matrix Mix
COMMON NAME:	Bone Void Filler Containing Human Demineralized Bone Matrix (DBM)
PROPOSED REGULATORY CLASS:	Class II
CLASSIFICATION IDENTIFICATION:	21 C.F.R. §888.3045 Resorable calcium salt bone void filler device
PRODUCT CODE:	MQV, GXP, MBP
SPONSOR:	Musculoskeletal Transplant Foundation 125 May Street Edison, NJ 08837 732-661-0202

INDICATIONS FOR USE:

DBX® is intended for use as a Demineralized Bone Matrix for voids or gaps that are not intrinsic to the stability of the bony structure. DBX® Putty, Paste, and Mix may be used in the extremities and pelvis. DBX® Putty may also be used in the posterolateral spine and cranium. DBX® is indicated for treatment of surgically created osseous defects or osseous defects created from traumatic injury. DBX® Putty can be used as an extender in the spine with autograft. DBX® can be used with bone marrow. DBX® is intended for single patient use only.

DEVICE DESCRIPTION:

DBX® is intended for single patient use only. DBX® Demineralized Bone Matrix is available in three forms: Paste, Putty and Mix. DBX® products are completely resorbable. DBX® Paste and Putty are composed of cadaveric cortical bone; the DBX® Mix is composed of cadaveric corticocancellous bone. The bone granules are mixed with sodium hyaluronate (NaHy) in varying combinations to form the DBX® Putty, Paste, and Mix. DBX® Putty is available in five sizes and DBX® Paste and Mix are available in four sizes.

SAFTEY AND EFFECTIVENESS INFORMATION:

This 510(k) was submitted for a change in the osteoinductivity assay for DBX® Putty. The fundamental scientific technology of the modified DBX® Putty, using *in vitro* testing as an alternative for *in vivo* testing for osteoinductivity, is the same as the technology for the unmodified predicate, DBX® (FDA cleared, K040262).

Biocompatibility of DBX® materials has been established through their long history of safe and effective clinical use, further supported by laboratory testing conducted per ISO 10993. DBX® is single-donor processed using aseptic techniques and is tested for sterility per current USP <71>.

OSTEOINDUCTIVE POTENTIAL

DBX® Demineralized Bone Matrix is osteoconductive, and has been shown to have osteoinductive potential in an athymic mouse model.

Every lot of final DBX® Paste and DBX® Mix product will be assayed *in vivo* for osteoinductive potential. Standard testing performed in an athymic mouse must prove positive for lot release.

Every lot of final DBX® Putty product will be tested in an athymic mouse model or in an alkaline phosphatase assay, which has been shown to have a positive correlation with the athymic mouse model, to ensure the osteoinductive potential of the final product.

It is unknown how the osteoinductive potential, measured in the athymic mouse model or the alkaline phosphatase assay, will correlate with clinical performance in human subjects.

VIRAL CLEARANCE AND INACTIVATION:

This 510(k) was submitted for a change in the osteoinductivity assay for DBX® Putty. The fundamental scientific technology of the modified DBX® Putty, using *in vitro* testing as an alternative for *in vivo* testing for osteoinductivity, is the same as the technology for the unmodified predicate, DBX® (FDA cleared, K040262).

The method for processing the DBM contained in DBX was evaluated for its viral inactivation potential. A panel of model potential human viruses representing various virus types, sizes, shapes, and genomes were evaluated. The DBM processing methods were determined to provide significant viral inactivation potential for a wide range of potential viruses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Musculoskeletal Tissue Foundation
% Nancy Bennewitz
Regulatory Submission Specialist
125 may Street
Edison, NJ 08837

DEC 28 2006

Re: K053218
Trade/Device Name: DBX® Demineralized Bone Matrix Putty, Paste, and Mix
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler devices
Regulatory Class: Class II
Product Code: MQV, MBP, GXP
Dated: September 27, 2006
Received: September 29, 2006

Dear Ms. Bennewitz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IV. INDICATIONS FOR USE

510(k) Number (if known): K053218

Device Name: DBX® Demineralized Bone Matrix Putty, Paste and Mix

Indications for Use:

DBX® is intended for use as a Demineralized Bone Matrix for voids or gaps that are not intrinsic to the stability of the bony structure. It can be used in the:

Paste and Mix	Putty
Extremities	Extremities
Pelvis	Pelvis
	Posterolateral spine
	Cranium

DBX® is indicated for treatment of surgically created osseous defects or osseous defects created from traumatic injury. DBX® Putty can be used as an extender in the spine with autograft. DBX® can be used with bone marrow.

DBX® is for single patient use only.

Prescription Use __X__ (Per 21 CFR 801 Subpart D) OR Over-The-Counter Use _____ (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K053218